UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,262	08/01/2001	Jill Giles-Komar	CEN0248	5697

27777 7590 06/30/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/920,262	Knight et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 1, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-101* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-3, 9-11, drawn to an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:7, classified in Class 530, subclass 387.9.

Group 2. Claims 1-3, 9-11, drawn to an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:8, classified in Class 530, subclass 387.9.

Group 3. Claims 4-8, 19-20, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:7, a vector, a host cell and a method of producing the protein, classified in Class 435, subclass 69.1.

Group 4. Claims 4-8, 19-20, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:8, a vector, a host cell and a method of producing the protein, classified in Class 435, subclass 69.1.

Group 5. Claims 12-17, drawn to a method for treating a IL-12 related condition by administering an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:7, classified in Class 424, subclass 145.1.

Group 6. Claims 12-17, drawn to a method for treating a IL-12 related condition by administering an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:8, classified in Class 424, subclass 145.1.

Group 7.Claims 12-17, drawn to a method for diagnosing a IL-12 related condition by administering an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:7, classified in Class 435, subclass 7.2.

Group 8.Claims 12-17, drawn to a method for diagnosing a IL-12 related condition by administering an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:8, classified in Class 435, subclass 7.2.

Group 9. Claim 18, drawn to a medical device comprising an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:7, Class and subclass undeterminable.

Group 10. Claim 18, drawn to a medical device comprising an anti-IL-12 antibody comprising the variable amino acid sequence set forth in SEQ ID NO:8, Class and subclass undeterminable.

Group 11. Claims 21-23, 29-31, drawn to an anti-IL-12 antibody comprising all of the heavy chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:7, 8, 9, classified in Class 530, subclass 387.9.

Group 12. Claims 21-23, 29-31, drawn to an anti-IL-12 antibody comprising all of the light chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:10, 11, 12, classified in Class 530, subclass 387.9.

Group 13. Claims 24-28, 39-40, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising all of the heavy chain complementarity determining regions(CDR) amino acid sequences

of SEQ ID NO:7, 8, 9, a vector, a host cell, and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 14. Claims 24-28, 39-40, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising all of the light chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:10, 11, 12, a vector, a host cell, and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 15. Claims 32-37, drawn to a method for treating an IL-12 related condition by administering an anti-IL-12 antibody comprising all of the heavy chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:7, 8, 9, classified in Class 424, subclass 145.1.

Group 16. Claims 32-37, drawn to a method for treating an IL-12 related condition by administering an anti-IL-12 antibody comprising all of the light chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:10, 11, 12, classified in Class 424, subclass 145.1.

Group 17. Claims 32-37, drawn to a method for diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising all of the heavy chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:7, 8, 9, classified in Class 435, subclass 7.2.

Group 18. Claims 32-37, drawn to a method for diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising all of the light chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:10, 11, 12, classified in Class 435, subclass 7.2.

Group 19. Claim 38, drawn to a medical device comprising an anti-IL-12 antibody comprising all of the heavy chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:7, 8, 9, Class and subclass undeterminable.

Group 20. Claim 38, drawn to a medical device comprising an anti-IL-12 antibody comprising all of the light chain complementarity determining regions(CDR) amino acid sequences of SEQ ID NO:10, 11, 12, Class and subclass undeterminable.

Group 21. Claims 41-43, 49-51, 60-63, 69-71, 80, drawn to an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:1, classified in Class 530, subclass 387.9.

Group 22. Claims 41-43, 49-51, 60-63, 69-71, 80, drawn to an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:2, classified in Class 530, subclass 387.9.

Group 23. Claims 41-43, 49-51, 60-63, 69-71, 80, drawn to an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:3, classified in Class 530, subclass 387.9.

Group 24. Claims 41-43, 49-51, 60-63, 69-71, 80, drawn to an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:4, classified in Class 530, subclass 387.9.

Group 25. Claims 41-43, 49-51, 60-63, 69-71, 80, drawn to an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:5, classified in Class 530, subclass 387.9.

Group 26. Claims 41-43, 49-51, 60-63, 69-71, 80, drawn to an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:6, classified in Class 530, subclass 387.9.

Group 27. Claims 44-48, 59, 64-68, 79, drawn to a nucleic acid encoding an anti-IL-12 antibody, comprising the amino acid sequence of SEQ ID NO:1, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 28. Claims 44-48, 59, 64-68, 79, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:2, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 29. Claims 44-48, 59, 64-68, 79, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:3, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 30. Claims 44-48, 59, 64-68, 79, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:4, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 31. Claims 44-48, 59, 64-68, 79, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:5, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 32. Claims 44-48, 59, 64-68, 79, drawn to a nucleic acid encoding an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:6, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 33. Claims 52-57, 72-77, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:1, classified in Class 435, subclass 7.2.

Group 34. Claims 52-57, 72-77, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:2, classified in Class 435, subclass 7.2.

Group 35. Claims 52-57, 72-77, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:3, classified in Class 435, subclass 7.2.

Group 36. Claims 52-57, 72-77, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:4, classified in Class 435, subclass 7.2.

Group 37. Claims 52-57, 72-77, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:5, classified in Class 435, subclass 7.2.

Group 38. Claims 52-57, 72-77, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:6, classified in Class 435, subclass 7.2.

Group 39. Claims 52-57, 72-77, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:1, classified in Class 424, subclass 145.1.

Group 40. Claims 52-57, 72-77, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:2, classified in Class 424, subclass 145.1.

Group 41. Claims 52-57, 72-77, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:3, classified in Class 424, subclass 145.1.

Group 42. Claims 52-57, 72-77, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:4, classified in Class 424, subclass 145.1.

Group 43. Claims 52-57, 72-77, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:5, classified in Class 424, subclass 145.1.

Group 44. Claims 52-57, 72-77, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:6, classified in Class 424, subclass 145.1.

Group 45. Claims 58, 78, drawn to a medical device comprising an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:1, Class and subclass undeterminable.

Group 46. Claims 58, 78, drawn to a medical device comprising an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:2, Class and subclass undeterminable.

Group 47. Claims 58, 78, drawn to a medical device comprising an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:3, Class and subclass undeterminable.

Group 48. Claims 58, 78, drawn to a medical device comprising an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:4, Class and subclass undeterminable.

Group 49. Claims 58, 78, drawn to a medical device comprising an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:5, Class and subclass undeterminable.

Group 50. Claims 58, 78, drawn to a medical device comprising an anti-IL-12 antibody comprising the amino acid sequence of SEQ ID NO:6, Class and subclass undeterminable.

Group 51. Claims 81-83, 89-91, 100, drawn to an IL-12 antibody that binds the amino acid sequence of SEQ ID NO:9, classified in Class 530, subclass 387.9.

Group 52. Claims 84-88, 99, drawn to a nucleic acid encoding an IL-12 antibody that binds to the amino acid sequence of SEQ ID NO:9, a vector, a host cell and a method of producing the antibody, classified in Class 435, subclass 69.1.

Group 53. Claims 92-97, drawn to a method of treating an IL-12 related condition by administering an anti-IL-12 antibody that binds to the amino acid sequence of SEQ ID NO:9, classified in Class 424, subclass 145.1.

Group 54. Claims 92-97, drawn to a method of diagnosing an IL-12 related condition by administering an anti-IL-12 antibody that binds to the amino acid sequence of SEQ ID NO:9, classified in Class 435, subclass 7.2.

Group 55. Claim 98, drawn to a medical device comprising an anti-IL-12 antibody that binds to the amino acid sequence of SEQ ID NO:9, Class and subclass undeterminable.

Applicants are advised that claim 101 is an omnibus claim in that it fails to point out what is included or excluded by the claim language. See Ex parte Fressola, 27 USPQ2d 1608 (Bd. Pat. App. & Inter. 1993). See MPEP.. 2173.05(r). Therefore, this claim has not been included with any of the recited Groups.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-2, 3-4, 11-12, 13-14, 21-26, 27-32, 51-52, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotides of the inventions can be used to make hybridization probes or can be used in gene therapy as well as in the production of the specific proteins of interest. The antibodies of inventions can be used to obtain the polynucleotides, and can also be used in diagnostics, e.g. as a probe in immunoassays. Each of the polynucleotides of each specific invention can be used to produce the specific antibody polypeptide. The polynucleotide of Group 3 can only be used to produce the antibody protein of Group 1 but not the antibody protein of Groups 2.

Inventions 3-4 and 1-2 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP. § 806.05(f)). In the instant case each of the antibody proteins can be prepared by materially different processes, such as by chemical synthesis.

Inventions 13-14 and 11-12 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP. § 806.05(f)). In the instant case each of the antibody proteins can be prepared by materially different processes, such as by chemical synthesis.

Inventions 27-32, and 21-26 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP. § 806.05(f)). In the instant case each of the antibody proteins can be prepared by materially different processes, such as by chemical synthesis.

Inventions 52, and 51 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made

by another and materially different process (MPEP. § 806.05(f)). In the instant case the antibody protein can be prepared by a materially different process, such as by chemical synthesis

Inventions 1-2 and 7-8 are related as products and processes of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 1-2 can also be used in purifying the proteins of interest.

Inventions 11-12 and 1518 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 11-12 can also be used in purifying the proteins of interest.

Inventions 21-26 and 33-44 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 21-26 can also be used in purifying the proteins of interest.

Inventions 51 and 53-54 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of invention 51 can also be used in purifying the proteins of interest.

Inventions 3-4, 5-8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 13-14 and 15-18 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 27-32 and 33-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 51 and 53-54 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 5-8, 15-18, 33-44, 53-54 are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, different process steps and or materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 12, 2003